Date of IRB Review: May 2009
81st Medical Group
Keesler AFB, Mississippi

Exempt (Human) Research Protocol

This is a Progress Report ____ / Final Report __XX__

1. Protocol Number: FKE20060003E

2. Title: "Perinatal Morbidity and Mortality in the U.S. Department of Defense, 2001-2005"

3. Principal Investigator (PI): Andrew T. Allen, MD, Maj, USAF, MC, FS, 31 MSGS/SGCX, Phone: DSN 314-632-5863, Email: andrew.allen@aviano.af.mil
(Add your rank and full name, squadron/office symbol, telephone number, beeper number)

4. Purpose: *(Copy from your original protocol and paste here)* The risk of death from complications of pregnancy has decreased approximately 99% during the twentieth century, from approximately 850 maternal deaths per 100,000 live births in 1900 to 7.5 in 1982. However, since 1982, no further decrease has occurred in maternal mortality in the United States[1]. A recent study by Haas revealed a Maternal Mortality Ratio (MMR) of 5.5 per 100,000 live births within the Department of Defense during the period 1993-1998[2]. This is below the national average, but has not reached the goal of 3.3 per 100,000 set by Healthy People 2010[3].

The methods of data collection regarding maternal mortality are variable. The study by Haas cited above utilized Standard Inpatient Data Records (SIDR) from a military database. Other studies, such as performed by Berg, utilize the Center for Disease Control and Prevention's (CDC) Pregnancy-Related Mortality Surveillance System, which accesses data input from the different states' health departments as well as national death files[4].

Each system of data collection has its own merits and faults depending on the patient population as well as the ultimate use of the information. Extracting accurate information from such a large pool of data can be difficult as well, depending on the accuracy of the information input into each system. This is a well-known weakness of large epidemiological studies, and attempts to minimize such errors are crucial in the development of protocols and data collection instruments.

In 2000 the Department of Defense began using a new system for collecting and storing SIDR data, known as the M2 data repository. Each DOD institution (worldwide) inputs data from the Composite Health Care System (CHCS) into M2 on a regular basis, and information is available for retrieval going as far back as fiscal year 2000. The information collected by M2 is too vast to list in this proposal, but includes many demographic variables, disposition data, as well as diagnosis and procedure codes.

The M2 data repository contains a wealth of information that, when appropriately accessed, can lead to many useful and informative research protocols. We intend to use M2 in this study to determine the rates of maternal and neonatal morbidity and mortality within the U.S. Department of Defense military treatment facilities between 2001 and 2005.

Collecting and reporting this information will be valuable for all Military Treatment Facilities. The rates that will be determined can guide departmental Morbidity and Mortality conferences as well as Quality Assurance meetings in determining how their local facility compares to the rest of the Department of Defense facilities in each category.

5. Status of the Study. Mark the status of the study (a-e).

a. _____ Active with ongoing data collection. Request approval to remain open.

b. _____ Active with data collection complete. Request approval to remain open.

c. _____ Study was never initiated and request termination of the study.

d. __XX__ Completed, research implemented and results available. Request approval to close.

e. _____ Inactive, protocol never initiated, but want to keep in open. Request approval to remain open.

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
28 SEP 2010	**Final Report**	**00-00-2001 to 00-00-2005**

4. TITLE AND SUBTITLE
Perinatal Morbidity and Mortality in the U.S. Department of Defense, 2001-2005

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Andrew Allen

5d. PROJECT NUMBER
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5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The risk of death from complications of pregnancy has decreased approximately 99% during the twentieth century, from approximately 850 maternal deaths per 100,000 live births in 1900 to 7.5 in 1982. However, since 1982, no further decrease has occurred in maternal mortality in the United States. The M2 data repository was queried for all vaginal and cesarean births that occurred within all U.S. Department of Defense military treatment facilities from 1 Jan 2001 to 31 Dec 2005 by selecting all encounters that fell under the diagnosis related groups (DRGs) 370-375 (cesarean and vaginal deliveries, with and without complications, and with and without associated procedures). As the overall cesarean rate has increased and the rate of forceps deliveries has decreased, the rates of 3rd and 4th degree lacerations and shoulder dystocia have decreased (58.72 to 41.48 per 1,000 and 29.27 to 22.25 per 1,000 respectively, statistical significance not calculated). The rate of GBS infection has increased from 2001 to 2005 (137.27 to 200.17 per 1,000) which likely reflects the institution ofuniversal screening in 2002, not necessarily an increase in the rate of actual infection.

15. SUBJECT TERMS
Perinatal Morbidity and Mortality; M2;

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**1**	**5**	

6. Summary of Progress: This report covers the following period of time: August 2006 – May 2009.
Provide a brief summary of any results obtained in the study even if results are not yet statistically significant.

a. Since last progress report or initiation of study: I am finished collecting data.

b. For the entire study: I have completed 100% of the study.

c. If this is a FINAL REPORT:

1. Were the protocol objectives met and how will the outcome benefit the DoD/USAF? The objectives were met, and I review the results periodically to acertain rates of various delivery modes as well as morbidity. However, since the study was initiated, I became involved with the NPIC (National Perinatal Information Center). The PPIP (Perinatal Performance Information Project) gathers much of the same data that I had gathered, but analyzes it much more in-depth. Therefore, I defer further analysis to the NPIC and request to close the study. *(Answer……)*

2. Protocol Outcomes Summary:

Background: In 2000 the Department of Defense began using a new system for collecting and storing SIDR data, known as the M2 data repository. Each DOD institution (worldwide) inputs data from the Composite Health Care System (CHCS) into M2 on a regular basis, and information is available for retrieval going as far back as fiscal year 2000. The information collected by M2 is too vast to list in this paper, but includes many demographic variables, disposition data, as well as diagnosis and procedure codes. The purpose of this study was to use SIDR data from M2 to determine the rates of maternal morbidity and mortality within the U.S. Department of Defense military treatment facilities between 2001 and 2005.

Methods: The M2 data repository was queried for all vaginal and cesarean births that occurred within all U.S. Department of Defense military treatment facilities from 1 Jan 2001 to 31 Dec 2005 by selecting all encounters that fell under the diagnosis related groups (DRGs) 370-375 (cesarean and vaginal deliveries, with and without complications, and with and without associated procedures). Each encounter included the following variables: maternal age, race, beneficiary category, treatment facility, date of admission, date of delivery, and disposition status; as well as 8 associated International Classification of Disease (ICD-9) diagnosis codes, and 8 ICD-9 procedural codes. No personally identifiable information (such as patient name or social security number) was retrieved during this query. Each encounter's associated ICD-9 diagnosis and procedure codes were tabulated and cross-referenced using Microsoft Access, and Microsoft Excel calculated the rates of the various morbidities.

Results: It is interesting to note that the primary cesarean rate did not increase by much (15.30% to 16.88% from 2001-2005, statistical significance not yet calculated) but the overall cesarean rate has increased from 20.73% in 2001 to 24.30% in 2005, driven by an increase in the repeat cesarean rate (33.33% to 38.28%), decrease in the VBAC rate (28.58% to 16.70%), and decrease in the operative vaginal delivery rate (9.92% to 7.91%). The decrease in operative vaginal deliveries appears to be driven by a decrease in the rate of forceps from 2001 to 2005 (4.33% to 2.27%) as the rate of vacuum deliveries appears to be relative constant (5.41% to 5.54%). Statistical significance has not been calculated. As the overall cesarean rate has increased and the rate of forceps deliveries has decreased, the rates of 3rd and 4th degree lacerations and shoulder dystocia have decreased (58.72 to 41.48 per 1,000 and 29.27 to 22.25 per 1,000 respectively, statistical significance not calculated). The rate of GBS infection has increased from 2001 to 2005 (137.27 to 200.17 per 1,000) which likely reflects the institution of universal screening in 2002, not necessarily an increase in the rate of actual infection.

Rates of delivery

	Total	2001	2002	2003	2004	2005
Total Live Births:	***261,020***	**52,414**	**53,248**	**52,950**	**51,996**	**50,412**
Total Cesareans	***59,403***	**10,864**	**11,609**	**12,077**	**12,605**	**12,248**
Total Prior Cesareans	***27,919***	**5,070**	**5,680**	**5,712**	**5,828**	**5,629**
Primary Cesareans:	*37735*	7243	7423	7646	7864	7559
Repeat Cesareans:	*21668*	3621	4186	4431	4741	4689
Total Cesarean rate	*22.76%*	20.73%	21.80%	22.81%	24.24%	24.30%
Primary Cesarean rate	*16.19%*	15.30%	15.61%	16.19%	17.03%	16.88%
Repeat Cesarean rate	*36.48%*	33.33%	36.06%	36.69%	37.61%	38.28%
VBACs:	*6251*	1449	1494	1281	1087	940
VBAC rate	*22.39%*	28.58%	26.30%	22.43%	18.65%	16.70%
Total Vaginal	***201,617***	**41,550**	**41,639**	**40,873**	**39,391**	**38,164**
Forcep Deliveries	*6326*	1801	1456	1200	1002	867
Vacuum Deliveries	*11293*	2247	2286	2387	2259	2114
Forceps + Vacuum	*277*	74	43	56	65	39
Operative Deliveries	*17896*	4122	3785	3643	3326	3020
Forceps rate	*3.14%*	4.33%	3.50%	2.94%	2.54%	2.27%
Vacuum rate	*5.60%*	5.41%	5.49%	5.84%	5.73%	5.54%
Operative vaginal rate	*8.88%*	9.92%	9.09%	8.91%	8.44%	7.91%

Maternal morbidities, with rate per 1,000 live births

	Total	*Rate*	2001	Rate	2002	Rate	2003	Rate	2004	Rate	2005	Rate
Live Births:	***261,020***		**52,414**		**53,248**		**52,950**		**51,996**		**50,412**	
l cesarean	***59,403***		**10,864**		**11,609**		**12,077**		**12,605**		**12,248**	
l Vaginal	***201,617***		**41,550**		**41,639**		**40,873**		**39,391**		**38,164**	
lerance of labor	***92265***		**18509**		**18517**		**18318**		**18561**		**18360**	
:st disorder	***33197***		**6940**		**7128**		**6751**		**6122**		**6256**	
lpresentation	***14338***		**2983**		**2863**		**2902**		**2921**		**2669**	
ver/Septicemia	***15729***	*60.26*	**2964**	56.55	**3169**	59.51	**3254**	61.45	**3226**	62.04	**3116**	61.81
nnionitis	***11704***	*44.84*	**2173**	41.46	**2260**	42.44	**2366**	44.68	**2486**	47.81	**2419**	47.98
oulder dystocia	***5297***	*26.27*	**1216**	29.27	**1214**	29.16	**1111**	27.18	**907**	23.03	**849**	22.25
erine rupture	***227***	*0.87*	**45**	0.86	**50**	0.94	**56**	1.06	**34**	0.65	**42**	0.83
mniotic fluid embolism	***7***	*0.03*	**0**	0.00	**2**	0.04	**0**	0.00	**2**	0.04	**3**	0.06
ulmonary embolism	***40***	*0.15*	**6**	0.11	**6**	0.11	**15**	0.28	**5**	0.10	**8**	0.16
Cerebrovascular event	***42***	*0.16*	**9**	0.17	**8**	0.15	**10**	0.19	**5**	0.10	**10**	0.20
DVT	***110***	*0.42*	**19**	0.36	**21**	0.39	**17**	0.32	**30**	0.58	**23**	0.46
Postpartum hemorrhage	***12509***	*47.92*	**2644**	50.44	**2602**	48.87	**2568**	48.50	**2420**	46.54	**2275**	45.13
3rd/4th degree laceration	***9893***	*49.07*	**2440**	58.72	**2191**	52.62	**1897**	46.41	**1782**	45.24	**1583**	41.48
Uterine inversion	***106***	*0.53*	**20**	0.48	**29**	0.70	**24**	0.59	**18**	0.46	**15**	0.39
Vulvovaginal hematoma	***815***	*4.04*	**132**	3.18	**204**	4.90	**197**	4.82	**166**	4.21	**116**	3.04
Cervical laceration	***1115***	*5.53*	**223**	5.37	**194**	4.66	**219**	5.36	**324**	8.23	**155**	4.06

Maternal infections per 1,000 live births

	Total	*Rate*	2001	Rate	2002	Rate	2003	Rate	2004	Rate	2005	Rate
Total Live Births:	*261,020*		52,414		53,248		52,950		51,996		50,412	
Total cesarean	*59,403*		10,864		11,609		12,077		12,605		12,248	
Total Vaginal	*201,617*		41,550		41,639		40,873		39,391		38,164	
GBS	*45,088*	*172.74*	7,195	137.27	8,527	160.14	9,574	180.81	9,701	186.57	10,091	200.17
Herpes simplex	*3,632*	*13.91*	677	12.92	751	14.10	817	15.43	738	14.19	649	12.87
Syphilis	*51*	*0.20*	20	0.38	6	0.11	7	0.13	8	0.15	10	0.20
Tuberculosis	*48*	*0.18*	16	0.31	11	0.21	7	0.13	4	0.08	10	0.20
HIV/AIDS	*12*	*0.05*	5	0.10	1	0.02	2	0.04	3	0.06	1	0.02

(Please provide in abstract format a summary of the protocol objectives, materials, methods, and results. Include tables/figures, conclusions, and applications)

◄ IF THIS IS A FINAL REPORT PROCEED TO # 9 ►

7. Protocol Changes:

a. _____ No changes are anticipated and the project will continue as previously approved by the IRB.

b. _____ Changes are anticipated as described below: *(Description.....)*

c. When do you anticipate PCSing or separating? Indefinite

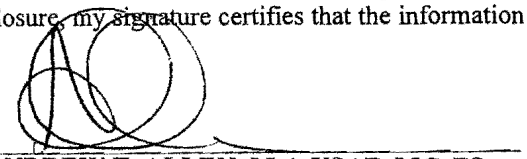
8. Protocol Personnel Changes: Has there been any Principal or Associate Investigator (PI/AI) changes since approval of protocol or the last continuation review? ____ Yes __XX__ No.

9. Status of Approved Funding: No funding was requested in my original protocol.

10. Publications/Presentations/Awards: N/A

11. Certification of Principal Investigator

My signature certifies that the above titled research has been conducted in full compliance with the HHS/FDA Regulations and IRB requirements/policies governing human subject research. I understand that a Progress Report is required in order to maintain continuation approval and any changes in the study/methodology must be approved by the IRB prior to implementation. If the study has never been initiated and I am requesting termination (Item 5.c. above), my signature certifies this request. If the study is completed (Items 5.d. & 6.c. above) and I am requesting closure, my signature certifies that the information provided on this form represents an accurate final report.



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